UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

In re NIASPAN ANTITRUST LITIGATION	**MDL No. 2460** **2:13-md-2460 JD**
THIS DOCUMENT RELATES TO: **All Direct Purchaser Class Actions**	**JURY TRIAL DEMANDED**

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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A brand name drug manufacturer should not pay a generic manufacturer not to compete. And a generic manufacturer should not accept payments to delay entry of its less-expensive product. Period. But that is precisely what the defendants did. Kos Pharmaceuticals, Inc., a brand name drug manufacturer, sued Barr Pharmaceuticals Inc., a generic manufacturer, to stop Barr from coming to market. Then Kos made an abrupt U-turn, abandoned its claims, and instead simply paid Barr not to enter the market for eight years, providing cold, hard cash and the promise of exclusivity in generic sales once the eight years ended. Kos got an extra eight years of monopoly profits from supracompetitive prices of its brand name drug, free from competition. Barr got hundreds of millions of dollars in payments and future profits on its eventual generic drug. And purchasers got artificially high prices for close to a decade longer than they otherwise would have.

Direct purchaser plaintiffs Professional Drug Company, Inc., Rochester Drug Co-Operative, Inc., and Value Drug ("direct purchaser plaintiffs") on behalf of themselves and all others similarly situated, for their complaint against the defendants Abbott Laboratories, AbbVie Inc. ("AbbVie"), (together with Abbott Laboratories, "Abbott"), Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries, Ltd., and Teva Women's Health, Inc. f/k/a Duramed Pharmaceuticals Inc. ("Duramed"), and Duramed Pharmaceuticals Sales Corp. ("DPSC") (collectively "Teva"), and Barr Pharmaceuticals Inc. ("Barr"), allege as follows based on: (a) personal knowledge; (b) the investigation of their counsel; and (c) information and belief.

INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the defendants' unlawful exclusion of generic substitutes for the brand drug Niaspan, which is extended-release niacin, a version of vitamin B3 used to help treat mixed lipid disorders and boost HDL ("good") cholesterol and lower LDL ("bad") cholesterol. Niacin pills have been used

since the 1930s and extended-release niacin has been sold as a prescription drug under the brand name Niaspan since 1997, first by Kos Pharmaceuticals, Inc. ("Kos") and later by Abbott and AbbVie, following various corporate mergers and restructuring. Although the first of would-be generic manufacturers began applying to market generic extended-release niacin in October 2001, no generic competitor would enter the market until September 2013, nearly twelve years later.

2. Defendants caused the delay. In 2005, Kos colluded with would-be generic manufacturer Barr and illegally delayed generic entry by paying Barr to (a) not enter the market until September 20, 2013 and (b) drop challenges to Kos' patents that ostensibly covered Niaspan. Kos' successors, Abbott and AbbVie, and Barr's successor, Teva, continued this illegal collusion and unreasonable restraint of trade in the market for extended-release niacin, all at the expense of purchasers. Every month of delay of generic competition allowed Kos and its successors to preserve many millions of dollars in monopoly profits from Niaspan without generic competition and allowed Barr and its successor to share in those profits by pocketing millions of dollars from Kos for agreeing to delay bringing generic extended-release niacin to market.

3. Beginning in early 2002, after Barr became the first generic manufacturer to seek approval from the Food and Drug Administration ("FDA") to market generic extended-release niacin, Kos sued Barr, accusing it of infringing on multiple patents ostensibly covering Niaspan. These suits automatically triggered a thirty-month stay on FDA approval, meaning that regardless of the merits of the patent infringement actions, the FDA could not grant final approval to Barr to launch its generic product until at least March 31, 2005. And foreclosing Barr from launching also foreclosed all other generic manufacturers; as the first manufacturer to

seek approval for generic extended-release niacin, Barr was entitled to 180 days of market exclusivity, free from competition from other generic manufacturers, once it actually launched its product.

4. Between early 2002 and early 2005, while the thirty-month stay was in effect, Barr fought the patent infringement suits and prepared to bring its generic extended-release niacin to market to compete with brand name Niaspan. In March 2005, Barr was ready. Barr had received tentative approval from the FDA for three different dosages of extended-release niacin in mid-2003, with final approval being subject only to expiration of the thirty-month stay. In the weeks and months leading up to March 2005, Barr began accumulating inventory that it would need to fill orders for its product as soon as launch occurred. All Barr needed was final FDA approval.

5. At the same time, the patent litigation continued. Launching before the conclusion of patent litigation under some circumstances poses risks; if the court finds the subject patent(s) valid, enforceable, and infringed, the generic company may face substantial damages from its sales of an infringing product. But Barr was so sure of the rightness of its actions – that Kos' Niaspan patents were invalid, unenforceable, or not infringed by Barr's product – that Barr planned to launch its generic extended-release niacin as soon as the FDA gave the final green light and despite the existing patent litigation.

6. Barr expected to receive this final green light in April 2005. And Barr was correct: on April 26, 2005, the FDA granted final approval for three dosages of Barr's generic extended-release niacin.

7. Barr was set to go – and competition would have begun – save for one thing: mere days earlier and not coincidentally, Kos and Barr colluded to halt generic competition and harm

purchasers. Rather than face one or more less-expensive generics on the market and the subsequent reduction in Niaspan sales and revenues such competition would cause, Kos paid Barr to stay off of the market for eight years. Kos' payments to Barr to exclude Barr's generic from the market took two primary forms: cash and an agreement not to launch a competing "authorized generic" version of Niaspan when Barr eventually launched its generic product in 2013. Barr readily accepted the exclusion payments, worth hundreds of millions of dollars, and stood down.

8. The scheme worked as planned. No generic extended-release niacin was sold until on or about September 20, 2013, far later than it would have been absent the defendants' illegal, anticompetitive conduct. And even now, only one generic version of extended-release niacin is available – still at non-competitive prices – since additional generics are further foreclosed until March 2014, after Barr's exclusivity period lapses.

9. Had Barr (or its successor) launched a generic version of Niaspan at any time before September 20, 2013, extended-release niacin would have sold at lower prices than the prices at which Kos (or its successors) was selling Niaspan. Direct purchaser plaintiffs would have paid lower prices – on both brand name Niaspan and its generic equivalents – than they actually paid.

10. Had Kos (or its successors) launched its authorized generic equivalent of Niaspan when Barr (or its successor) launched, prices for brand name Niaspan and its generic equivalents would have dropped even lower. As a matter of pharmaceutical economics, prices fall most dramatically when two or more generic equivalents of a drug are on the market alongside a brand name product. Direct purchaser plaintiffs would have paid even lower prices – on both brand name Niaspan and its generic equivalents – than they actually paid.

11. Had Barr launched earlier at-risk, via settlement, or after victory in the patent litigation, other generic manufacturers with ANDAs for generic equivalents of Niaspan would have been permitted to launch their own products following the lapse of Barr's 180-day exclusivity period. By delaying Barr's launch until September 20, 2013, Kos and Barr sought to prevent – and have succeeded in preventing – other generic manufacturers from launching until 2014.

12. Defendants' scheme to delay competition in violation of the federal antitrust laws caused the direct purchaser plaintiffs and members of the class to pay hundreds of millions of dollars more for extended-release niacin products than they would have paid absent such conduct.

JURISDICTION AND VENUE

13. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by the direct purchaser plaintiffs and members of the class (defined below) resulting from the defendants' unlawful foreclosure of the United States market for extended-release niacin. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

14. Defendants transact business within this District, and they carry out interstate trade and commerce in substantial part in this District and/or have an agent and/or can be found in this District. Venue is therefore appropriate within this District under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

PARTIES

A. Direct purchaser plaintiffs

15. Plaintiff Professional Drug Company, Inc. ("Professional Drug") is a corporation

organized under the laws of the State of Mississippi, with its principal place of business located at 186 Bohn Street, Biloxi, Mississippi 39530. Professional Drug purchases pharmaceuticals directly from manufacturers and then sells them to indirect purchasers. Professional Drug purchased brand Niaspan and generic extended-release niacin directly from one or more of the defendants during the proposed class period and was injured by their anticompetitive conduct.

16. Plaintiff Rochester Drug Co-Operative, Inc. ("Rochester Drug") is a stock corporation organized under the laws of the state of New York and is located at 50 Jet View Drive, Rochester, New York 14624. Rochester Drug purchased Niaspan and generic extended-release niacin directly from one or more of the defendants during the proposed class period and was injured by their anticompetitive conduct.

17. Plaintiff Value Drug Company ("Value Drug") is a corporation organized under the laws of the Commonwealth of Pennsylvania and is located at One Golf View Drive, Altoona, Pennsylvania 16601. Value Drug purchased Niaspan and generic extended-release niacin directly from one or more of the defendants during the proposed class period and was injured by their anticompetitive conduct.

B. Defendants

18. Defendant Abbott Laboratories is a corporation organized and existing under the laws of the state of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott purchased Kos Pharmaceuticals, Inc. in a tender offer transaction in 2006. On or about on January 1, 2013, Abbott spun off most of its pharmaceuticals operations to AbbVie Inc.

19. Defendant AbbVie Inc. is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois.

20. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

21. Defendant Teva Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, Israel. Teva is a leading manufacturer of generic drugs and one of the largest sellers of generic drugs in the United States. Teva purchased Barr Pharmaceuticals Inc. in 2008 and Barr is now a wholly-owned subsidiary of Teva.

22. Defendant Barr Pharmaceuticals Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Prior to 2004, Barr was known as Barr Laboratories, Inc. In 2008, Barr became a wholly-owned subsidiary of Teva.

23. Defendant Duramed Pharmaceuticals Inc. is a corporation organized under the laws of the state of Delaware, with principal places of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In 2008, when Teva purchased Barr, Duramed became a subsidiary of Teva. Duramed, along with Duramed Pharmaceuticals Sales Corp., is now known as Teva Women's Health, Inc.

24. Defendant Duramed Pharmaceuticals Sales Corp. is a corporation organized under the laws of the state of Delaware, with principal places of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, DPSC was a subsidiary of Barr. In 2008, when Teva purchased Barr, DPSC became a subsidiary of Teva and, along with Duramed, became known as Teva Women's Health, Inc.

25. Although not named as a defendant, Kos Pharmaceuticals, Inc. was one of the

initiators of the unlawful scheme described in this complaint. Kos was a corporation organized under the laws of the state of Florida, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. In 2006, Kos was merged into Abbott, which became the successor to all of Kos' unlawful conduct described in this complaint.

26. Although not named as a defendant, Kos Life Sciences, Inc. was one of the initiators of the unlawful scheme described in this complaint. Kos Life Sciences Inc. was a corporation organized under the laws of the state of Delaware, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. Kos Life Sciences Inc. was a wholly-owned subsidiary of Kos. In 2006, when Kos was merged into Abbott, Kos Life Sciences Inc. became a Division of Abbott Laboratories, and Abbott became the successor to all of Kos Life Sciences Inc.'s unlawful conduct described in this complaint.

27. All of the defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

REGULATORY AND ECONOMIC BACKGROUND

A. Generic drugs benefit purchasers.

28. Generic competition enables purchasers, at all levels of the pharmaceutical supply chain, to purchase (a) generic versions of a brand name drug at a substantially lower price than the brand name drug, and (b) the brand name drug at a reduced price. Generic competition to a single brand name drug product can result in billions of dollars in savings to consumers, insurers, pharmacies, and other drug purchasers.

29. Orally available solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for approval as a generic version of a brand drug are assigned an "AB" rating by the FDA. The "AB" rating permits the generic drug to be substituted for the brand name drug at the pharmacy counter.

30. All states permit (and some states require) pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug to substitute for and otherwise compete with the brand name drug; until a generic manufacturer enters the market, the brand name manufacturer can charge supracompetitive prices without losing all or a substantial portion of its brand name sales.

31. Consequently, brand name drug manufacturers have a strong incentive to use various tactics, including exclusion payment agreements like that alleged here, to delay the introduction of generic competition into the market.

32. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their brand name counterparts. Many consumers routinely switch from a brand name drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their brand name counterparts' sales, causing a substantial reduction of the brand name drug's unit and dollar sales.

33. Typically, the first AB-rated generic drug is priced significantly below its brand name counterpart. As more AB-rated generics enter the market, prices for generic versions of the drug predictably decrease even further because of competition among the generic

manufacturers and pharmacy substitution; as a result, the loss of sales volume by the brand name drug to the generics accelerates. Generics are usually at least 25% less expensive than their brand counterparts when there is a single generic competitor, and this discount typically increases to 50% to 90% (or more) when there are multiple generic competitors on the market for a given brand.

34. Once a generic equivalent hits the market, the generic quickly captures sales of the brand name drug, often capturing 80% or more of the market within the first six months. The Federal Trade Commission has calculated that about one year after market entry, the generic version on average takes 90% of the brand's unit sales and sells for 15% of the price of the brand name product.

35. Brand name manufacturers are well aware of generics' rapid erosion of their previously monopolized market. Brand name manufacturers thus seek to extend their monopoly for as long as possible, sometimes through illegal means.

B. The FDA oversees new drug approvals and allows manufacturers to list, but does not check the validity of, patents covering their products in the Orange Book.

36. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must apply for FDA approval to sell the new drug by filing a New Drug Application ("NDA").[1] An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[2]

37. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand name manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the

[1] 21 U.S.C. §§ 301-392.

[2] *Id.* at §§ 355(a) & (b).

brand name drug in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."[3] Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance.[4]

38. The FDA relies completely on the brand name manufacturer's truthfulness about patent validity and applicability, as it lacks both the resources and the statutory authority to evaluate the validity, accuracy, or applicability of the patent. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The federal government encourages and facilitates the approval of generic drugs through the Hatch-Waxman Amendments to the FDCA.

39. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments to the FDCA, changed the approval standards for generic drugs, simplifying the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[5]

40. A generic manufacturer seeking approval to sell a generic version of a brand name drug may file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand name manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug, and is absorbed at the same rate and to the same extent as the brand drug – that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug.

41. The FDCA and Hatch-Waxman Amendments operate on the scientific principle

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[3] *Id.* at §§ 355 (b)(1) and (c)(2).

[4] 21 U.S.C. §§ 355(b)(1) & (c)(2).

[5] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug is present in the blood of a patient at the same extent and for the same amount of time as the brand name counterpart.[6]

42. Congress enacted the Hatch-Waxman Amendments and associated ANDA approval process to expedite the entry of generic drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical companies' incentives to create new and innovative products by providing regulatory exclusivities and patent term extensions that delay the onset of generic competition.

43. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand name and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion, with generic drugs accounting for 75% of prescriptions.

D. Generic manufacturers must certify that their product will not infringe the patents listed in the Orange Book.

44. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book

[6] 21 U.S.C. § 355(j)(8)(B).

or that the patents are invalid. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand name drug has expired (a "Paragraph II certification");

c. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").[7]

45. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer can delay FDA approval of the generic drug ANDA simply by suing the ANDA applicant for patent infringement, even though the generic product is not yet on the market. If the brand name manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the thirty-month stay. (This right to immediately initiate litigation and automatically garner a thirty-month stay of FDA approval of the ANDA stems directly from the brand name manufacturer's listing of one or more

[7] 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

patents in the Orange Book, with no determination by any agency that the listing is valid or legitimate.)

46. As an incentive to spur generic companies to seek approval of generic alternatives to brand name drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug: 180 days of market exclusivity – *i.e.*, all AB-rated generics by other generic manufacturers are kept off the market for at least six months.

47. An ANDA first-filer's 180-day exclusivity period will only be triggered upon the earlier of (a) the first-filer's commercial launch, or (b) entry of a final judgment from a court decision of invalidity, unenforceability, or non-infringement. That is, the FDA will not approve any subsequently-filed ANDA until the first-filer's 180-day exclusivity period has run, which (absent a final judgment on a relevant court decision) will not occur until 180 days after the first-filer launches its product – even if the launch is delayed.

E. Brand name manufacturers can sell an "authorized" generic to compete with traditional generic manufacturers.

48. There is one important relevant exception to the 180-day exclusivity period for the first generic filer: the brand name manufacturer is free to, and typically does, launch an "authorized generic" during the 180 day exclusivity period to compete on price with the first generic entrant. In this way the first-filer exclusivity period is somewhat of a misnomer because while later ANDA-approved generic manufacturers must wait six months after the first-filer's market entry to get FDA approval, a brand's authorized generic may enter at any time.

49. An authorized generic is the brand name drug, manufactured just like the brand name product, but sold as a generic product under the same approval as the brand product's original NDA. Because the brand name manufacturer already has approval to sell its brand name

drug, it does not need to file an ANDA, or obtain any additional approvals, to market an identical generic version of its own brand drug.

50. For the brand company, an authorized generic launch during the 180-day exclusivity period provides a low cost, low risk means to regain some of the revenue lost from the termination of brand exclusivity that would otherwise go to the generic first-filer. An authorized generic is pro-competitive and pro-consumer where it competes with another generic; it provides additional competition and thus lowers prices. But generic manufacturers view authorized generics simply as unwelcome competition. Generic manufacturers generally make about 80% of their total income on a given generic product during the 180-day exclusivity period. If there is no authorized generic, the generic manufacturer will capture 100% of generic sales during this period and can keep its generic price fairly high. The presence of an authorized generic during the 180-day exclusivity period slashes those sales; the first-filer can only expect to capture 50% of total generic sales – and at lower prices because of the increased competition – during that period.[8] Freedom from an authorized generic during the initial 180-day period is thus very valuable to the generic manufacturer holding that exclusivity: it more than doubles the generic manufacturer's revenues and profits for the drug.

F. The regulatory scheme is susceptible to abuse.

51. Brand name and generic manufacturers have enormous incentives to "game the system" and forestall generic competition. This can occur in a variety of ways.

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[8] In a report by the Federal Trade Commission issued at the request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, the FTC analyzed documents and empirical data covering more than 100 companies and found that the presence of authorized generic competition can reduce the first-filer generic's revenues by more than 50 percent during the 180-day exclusivity period. The FTC found that a generic company makes significantly less when competing with an authorized generic because the authorized generic takes a significant share of generic sales away from the first-filer, and wholesale and retail prices decrease when the first-filer faces an authorized generic.

52. First, brand name manufacturers often (a) list patents in the Orange Book even if such patents are not eligible for listing (or are invalid) and then (b) sue any generic manufacturer that files an ANDA with a Paragraph IV certification – even if the competitor's product does not actually infringe the listed patents or the patents are invalid or not enforceable – simply to delay final FDA approval of the ANDA for up to thirty months.

53. Any patent listed in the Orange Book provides a guise for filing a patent infringement suit. Even when those patents (a) do not cover the drug, (b) are not the type of patents that could be asserted in a patent infringement action, or (c) cannot be expected to hold up under the disinfecting sunshine of a patent infringement suit, the mere filing of a suit can substantially delay any generic from coming to market for up to thirty months (and possibly longer). As the FDA recognizes, "[t]he process of patent certification, notice to the NDA holder and patent owner, a 45-day waiting period, possible patent infringement litigation and the statutory 30-month stay mean there is the possibility of a considerable delay in the approval of ANDAs as a result of new patent listings."

54. According to a report by the Federal Trade Commission, as of June 1, 2002, generic manufacturers prevailed in Paragraph IV litigation in nearly three-quarters of all such cases involving a decision by the court, by obtaining a judgment of invalidity or non-infringement.[9]

55. Second, brand name and generic manufacturers sometimes abuse the regulatory scheme by agreeing to "settle" the Paragraph IV litigation with an exclusion payment: the brand manufacturer pays the first-filer generic manufacturer to stay off the market, thus (a) withdrawing that competitive threat from the market, and (b) at times, "bottlenecking" approval

[9] Generic Drug Entry Prior to Patent Expiration: An FTC Study, Federal Trade Com'n, July 2002 at 16, *available at* http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study.

for other would-be generic competitors. The unlawful preservation of the enormous, monopoly profits enjoyed by brand name manufacturers provides ample revenue to permit the brand name manufacturers to share some of their profits with the conspiring generic competitors, rather than having the total revenues available for both parties lessened by the falling prices that generic competition would engender.

56. A drug patent settlement in which the brand name manufacturer pays the generic manufacturer to drop a patent challenge has anticompetitive results. A generic drug may enter at a later point in time than it otherwise would. Or an invalid patent may remain unchecked to slow other generic entrants. Because the first-filed generic is entitled to 180 days of market exclusivity (as to other generics), some agreements push off the entry date of the first generic filer; this tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited. The brand name manufacturer benefits by holding on to its monopoly for longer and the generic manufacturer benefits by receiving compensation from the brand name manufacturer while still retaining its own period of exclusivity. But purchasers suffer by not having access to more affordable generics.

57. Third, a generic manufacturer holding 180-day exclusivity may delay its market entry in return for a brand name manufacturer's agreement not to launch an authorized generic during the 180-day exclusivity period. The agreement not to launch an authorized generic is an exclusion payment, lucrative for both parties. Although the brand name manufacturer will lose revenue and profits that it would otherwise make from the authorized generic product by making this deal, it retains far more in brand name profits from the sales it makes during the period of generic delay that it buys with the exclusion payment and its agreement to forego launching an

authorized generic. The generic manufacturer also wins by maintaining, when it finally launches, 100% of generic sales at higher prices rather than the 50% of total generic sales at lower prices it would garner in the face of an authorized generic during the 180-day exclusivity period. But purchasers are twice victimized: first by paying the brand name drug monopoly prices for longer than they otherwise would have and second by paying supracompetitive generic prices because of the absence of an authorized generic.

58. In its 2011 report entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, the Federal Trade Commission concluded that no-authorized-generic agreements can provide significant value to a first-filer generic manufacturer and have become a common form of payment from brand name to generic manufacturers to induce delayed generic entry. For the first-filer generic manufacturer, like Barr, of a brand name product like Niaspan, the difference between selling the only generic product and competing against an authorized generic during the exclusivity period can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's report cites numerous documents from industry participants confirming the financial impact of an authorized generic. No-authorized-generic agreements like the one between Kos and Barr thus allow competitors to benefit from an agreement not to compete and deny purchasers the lower prices that should flow to them from increased competition.

FACTUAL ALLEGATIONS

A. Niaspan accounted for the vast majority of Kos' revenues, profits, and market capitalization.

59. Niacin is vitamin B3. It was discovered in the late 1800s, appears naturally in many foods and started being sold as a dietary supplement in the United States beginning in the 1930s. In proper dosages, niacin will raise levels of HDL cholesterol (the so-called "good"

cholesterol) in patients. However, at high levels, niacin causes a patient's skin to flush with redness and it may cause liver toxicity.

60. In the 1990s, Kos set out to develop a time-release version of niacin, which could (a) be marketed as a once-a-day therapy to boost HDL cholesterol in patients who needed treatment for cholesterol levels and (b) avoid the side effects associated with high dosages of niacin. Eventually, Kos developed Niaspan, a time-release version of niacin, which it intended to market as a brand name prescription drug. Importantly, Kos neither claimed to have discovered that niacin reduces cholesterol (that was documented in the 1950s) nor was the first company to make a sustained release niacin formulation. Kos simply created a formulation that had a release rate that helped minimize or avoid select side effects.

61. Kos was unable to patent the active ingredient in Niaspan under a compound patent, because niacin was not an innovative chemical compound. However, Kos sought and received seven patents to cover the formulation and method-of-use for Niaspan: Patent No. 6,080,428 (the '428 Patent); Patent No. 6,129,930 (the '930 Patent); Patent No. 6,406,715 (the '715 Patent); Patent No. 6,469,035 (the '035 Patent); Patent No. 6,676,967 (the '967 Patent); Patent No. 6,746,691 (the '691 Patent); Patent No. 6,818,229 (the '229 Patent). In addition, Kos purchased two more patents: Patent Nos. 5,126,145 and 5,268,181 (the '145 Patent and the '181 Patent).

62. Kos filed an NDA for Niaspan and received FDA approval on July 28, 1997 to market Niaspan for the treatment of mixed lipid disorders.

63. Over time, Kos submitted all nine of the above patents to the FDA for listing in the Orange Book.

64. In September of 1997, Kos went to market with Niaspan, eventually selling

Niaspan in dosages of 500 mg, 750 mg, and 1000 mg. Niaspan was the only once-a-day prescription formulation of extended-release niacin available for treating mixed lipid disorders. Because of its unique position, doctors prescribed Niaspan often, and the drug garnered hundreds of millions of dollars of sales.

65. In the early years, sales of Niaspan made up the vast majority of Kos' sales revenue because Kos had no other significant drugs in its portfolio. As the years progressed, Kos began to sell other drugs, but Niaspan always accounted for a substantial portion of Kos' sales revenues. Specifically, in those early years:

a. In 2001, Kos sold $87 million of Niaspan – 100% of the company's sales revenue for the year.

b. In 2002, Kos sold $146 million of Niaspan – 84% of the company's sales revenue for the year.

c. In 2003, Kos sold $226 million of Niaspan – 77% of the company's sales revenue for the year.

d. In 2004, Kos sold $319 million of Niaspan – 64% of the company's sales revenue for the year.

e. In 2005, Kos sold $435 million of Niaspan – 57% of the company's sales revenue for the year.

66. Kos (and later Abbott and AbbVie) had market power with respect to Niaspan. Indeed, on several occasions during those early years, Kos reported that it was able to raise prices on Niaspan (even though costs were not increasing) while simultaneously increasing its sales volumes on the drug.

B. Barr posed a competitive threat by preparing to bring a generic equivalent of Niaspan to market.

67. After conducting extensive research and analysis regarding the patents that Kos had registered and legal due diligence concerning potential infringement or invalidity of Kos' patents, spending over $2.3 million on that research in the process, Barr concluded that Kos'

patents were invalid or unenforceable or that Barr's generic product would not infringe the patents. Accordingly, on October 2, 2001, Barr submitted ANDA 76-250 to the FDA, seeking approval to market a generic equivalent of the 1000 mg dosage of Niaspan.

68. On January 15, 2002, Barr sent Kos a Paragraph IV certification with respect to the listed patents covering Niaspan in a 1000 mg dosage. In that Paragraph IV certification, Barr stated that its proposed extended-release niacin, a generic version of Niaspan, would not infringe any of Kos' patents then listed in the Orange Book, that Kos' patents were invalid, and/or that Kos' patents were unenforceable. Barr was the first company to file such a certification. As the first ANDA filer to make a Paragraph IV certification, Barr expected that it was entitled to an exclusive 180-day period (as against other generic manufacturers) to market its generic extended-release niacin once the FDA approved the ANDA.

69. Kos immediately saw Barr as a competitive threat, and sought to thwart Barr's efforts to bring a generic equivalent of Niaspan to market. President and CEO Adrian Adams promised that Kos would "vigorously enforce [its] patent rights in order to protect Kos' cholesterol products, which [Kos has] effectively pioneered entirely on [its] own."

70. On March 4, 2002, Kos sued Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-1683), alleging that Barr's proposed generic extended-release niacin and related Paragraph IV certification infringed upon the '428 Patent and the '930 Patent with respect to the 1000 mg dosage of Niaspan. By operation of law, the filing of that lawsuit triggered a thirty-month stay that prohibited the FDA from granting final approval to Barr to launch a generic equivalent of Niaspan.

71. In the months that followed, Kos filed two more patent infringement lawsuits against Barr relating to Niaspan.

72. On August 13, 2002, Kos filed a second patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-6409), this time alleging that Barr had infringed the '428 Patent and '930 Patent by filing ANDA 76-738 (with an accompanying a Paragraph IV certification) with respect to the 500 mg and 750 mg dosages of Niaspan.

73. On November 12, 2002, Kos filed a third patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-8995), this time alleging that Barr had infringed the '715 Patent by submitting a supplemental Paragraph IV certification (dated September 30, 2002) regarding Niaspan.

74. Those cases were all consolidated into one proceeding. Under the law as it existed at that time, each of those lawsuits triggered a new thirty-month stay, and the last of those thirty-month stays began to run on September 30, 2002 (the date of Barr's supplemental Paragraph IV certification). Thus, the FDA was stayed from granting Barr final approval for marketing any generic equivalent of Niaspan until March 31, 2005. (Congress amended the relevant statute in 2003, and no lawsuit filed after 2003 would result in a new thirty-month stay with respect to the approval of Barr's ANDAs and its proposed generic equivalent of Niaspan.)

75. On March 26, 2004, Kos filed a fourth patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 04-cv-1683), this time alleging that Barr had infringed the '967 Patent by filing Paragraph IV certifications with respect to Niaspan.

76. That fourth case was consolidated with the first three cases. In the consolidated proceeding, Barr filed counterclaims against Kos, seeking declaratory judgments that Barr's Paragraph IV certifications did not infringe any of the relevant patents held by Kos. Barr's

counterclaims also sought rulings that those patents were invalid or otherwise unenforceable.

77. On September 3, 2004, Barr filed an action against Kos in the United States District Court for the Southern District of New York (docketed as 04-cv-7086), seeking a declaratory judgment that Barr was not infringing the '691 Patent and/or that the '691 Patent was invalid or otherwise unenforceable. This fifth lawsuit was also consolidated with the other pending patent infringement actions.

78. While the patent suits were pending, and while the thirty-month stay was still in place from the first three lawsuits, the FDA gave Barr tentative approval to proceed to market with its generic extended-release niacin. Barr received tentative approval for its 1000 mg product on May 9, 2003 and received tentative approval for its 500 mg and 750 mg products on June 13, 2003. Barr expected to receive final approval from the FDA shortly after the last of the thirty-month stays expired – that is, shortly after March 31, 2005. (In this complaint, unless indicated otherwise, "Niaspan" or "extended-release niacin" refers to all of the dosages of the drug.)

79. The patent lawsuits continued for more than two years without any substantive rulings on the merits of the patent claims. The court issued no claims construction rulings and no summary judgment rulings. On December 3, 2004, the court scheduled a trial for the consolidated cases for January of 2006.

C. Barr prepared to launch a generic equivalent of Niaspan at-risk in the spring of 2005.

80. As 2004 was drawing to a close, Barr was preparing to launch its generic extended-release niacin "at-risk": shortly after the thirty-month stay expired but before the patent litigation was resolved. Launching before resolution of the patent infringement litigation is considered "at-risk" because the generic manufacturer can risk incurring substantial damages if

the patent litigation results in a favorable ruling for the brand name manufacturer. A generic manufacturer must thus be sure of its footing to plan for or attempt an "at-risk" launch.

81. By the spring of 2005, Barr was ready and willing, and would have been able, to launch its generic extended-release niacin as soon as the FDA approved Barr's ANDA. Reports concerning Barr's anticipated impending at-risk launch caused Kos' shares to drop 13% in December of 2004.

82. Barr's at-risk launch would have brought a generic to market in the spring of 2005, without regard for the strength of the claims in the pending patent lawsuits, and without regard to the expiration dates on any of Kos' patents. And Barr retained its 180-day exclusivity period, free from competition from other generic manufacturers.

83. Kos saw the prospect of an at-risk launch by Barr as a growing competitive threat and acted swiftly in response.

84. Kos began preparing to launch its own authorized generic version of Niaspan, which would (a) deprive Barr of 180 days of exclusivity as the sole generic on the market and (b) replace some of Kos' lost brand revenues with those from authorized generic sales. Kos began manufacturing this authorized generic version of Niaspan to have inventory on hand to sell as soon as Barr launched at-risk. By the end of the first quarter of 2005, Kos had accumulated substantial inventory for its authorized generic launch. Kos was prepared to launch – and would have launched – an authorized generic version of Niaspan in early 2005 if Barr had launched its generic extended-release niacin product at-risk.

85. On March 7, 2005, Kos sought a preliminary injunction to prohibit Barr from proceeding with its at-risk launch of generic Niaspan. The court held a hearing on Kos' application for a preliminary injunction on March 18, 2005.

86. At the time of the March 18th hearing, Barr was ready to launch its generic equivalent of Niaspan and was accumulating inventory that it would need to fill orders for its generic product as soon as the launch occurred. Barr was waiting only for the FDA to issue final approval, which Barr expected to receive in April 2005.

87. But both Kos and Barr had enormous incentives to settle the patent infringement litigation and avoid competition. Niaspan constituted the vast majority of Kos' company-wide sales revenue from 2001 through 2005; losing a substantial portion of that revenue stream – as Kos would have if the patents were held by a court to be invalid, unenforceable, or not-infringed – would have drastically affected its profits. And without a substantial revenue stream from Niaspan, Abbott would have paid vastly less for Kos the next year. Kos, therefore, was desperate to settle the patent litigation with Barr. Even Barr acknowledged that the patent infringement litigation "was literally 'bet-the-company' for Kos because Niaspan provided over 80 percent of the company's profits to support its $1.8 billion market capitalization."

88. Barr, too, desired to settle the patent litigation. Barr knew that it would be more profitable to be paid not to compete than to enter the market. Barr's profits during its 180-day exclusivity period would plummet if Kos had launched an authorized generic during that time, as Kos was preparing to do. The competition among multiple generics would have driven down the price of generic Niaspan. Once there are multiple generic versions of the same brand drug available, the generic behaves like a commodity, with little to distinguish one generic from another except price. While such competitive generic sales are still profitable, it can be substantially more profitable to be paid by the brand company not to compete. Barr knew that, rather than entering the market and competing, it could make more profit by agreeing to delay entry in exchange for a portion of Kos' monopoly profits from Niaspan, paid in the form of an

Exclusion Payment.

D. In late March 2005, Kos and Barr entered into the Exclusion Payment Agreement, agreeing that Barr would not launch a generic competitor to Niaspan for more than eight years.

89. On March 30, 2005 – before the court ruled on Kos' application for a preliminary injunction – Kos and Barr announced that they had "settled" the patent litigation and asked the court to postpone any ruling on that application so that they could formalize their settlement. The court issued a Conditional Order of Discontinuance on March 30, 2005.

90. Kos agreed to pay Barr – the purported infringer – to settle the patent litigation in March of 2005 because Barr was ready to launch – and was going to do so in April of 2005. Niaspan was too important to Kos' viability and valuation and the prospect of even an at-risk launch by Barr posed too great a threat to the pricing of Niaspan to allow generic competition; Kos needed to prevent generic entry so that it could continue to charge higher prices and continue to sell high volumes of Niaspan.

91. Kos used the strength of its wallet as opposed to the strength of its patents to obtain Barr's agreement not to launch its generic version of Niaspan. Recognizing the substantial likelihood that its Niaspan patents would be invalidated and/or that the generics' products would be adjudged non-infringing, Kos agreed to share its monopoly rents with Barr as the *quid pro quo* for Barr's agreement not to compete with Kos in the extended-release niacin market until September 20, 2013.

92. As the Supreme Court recently explained in a similar case involving such a reverse or exclusion payment, Kos' patents that purportedly cover Niaspan "may or may not be valid, and may or may not be infringed. '[A] *valid* patent excludes all except its owner from the use of the protected process or product[.]' And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an *invalidated* patent

carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe."[10] The payment can "provide a workable surrogate for [the] patent's weakness[.]"[11] "An unexplained large reverse payment" – like the payment at issue here – "itself would normally suggest that the patentee has serious doubts about the patent's survival."[12]

93. Under the agreement not to compete (the "Exclusion Payment Agreement"), Kos agreed to make continuing substantial unlawful payments to Barr over a period of eight years and, for those payments, Barr unlawfully agreed to refrain from launching a generic equivalent of Niaspan until September 2013. That agreement preserved Niaspan's dominant position in the market, while sharing some of the supracompetitive revenues resulting from that dominant position.[13] Kos and Barr cloaked the payments behind a spurious supply agreement and an equally spurious promotion agreement, but the payments to Barr (and later Teva) far exceeded the fair value of any services that the generic company would provide under those agreements (including the fact that Kos did not need Barr to provide the services). The real purpose for making the payments was to induce Barr (and later Teva) to delay from competing with Niaspan.

94. As part of the Exclusion Payment Agreement, on April 12, 2005, Kos and Barr executed three contracts that facilitated and helped effectuate their unlawful Agreement. Those three contracts were as follows:

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[10] *See FTC v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223, 2231 (2013) (citation omitted).

[11] *See id.* at 2236-37.

[12] *Id.* at 2236. A "large" payment is one that exceeds the brand/patentee's litigation costs saved by entering into its agreement with the generic. *Id.* The reverse payments at issue here easily meet that criterion.

[13] The Exclusion Payment Agreement also included terms relating to Kos' drug Advicor, a drug for which Barr had not yet even filed an ANDA. Defendants' agreement covering Advicor is memorialized in the Niaspan Exclusion Payment Agreement and incorporates the same key terms – including Barr's agreement not to launch a generic version of Advicor until September 2013 and Kos' agreement not to launch an authorized generic form of Advicor. The inclusion of the Advicor product is a further payment to Barr for its agreement not to launch generic Niaspan.

a. **Settlement and Licensing Agreement.** Kos and Barr agreed to drop all claims and counterclaims pending against each other in the patent lawsuits. Kos gave Barr a license for all of the patents arguably covering Niaspan on the condition that Barr would not bring a generic equivalent of Niaspan to market until September 20, 2013 (or such earlier time as may be required to preserve Barr's right to market a generic exclusively for 180 days).[14] Kos also agreed that it would not launch an authorized generic version of Niaspan after Barr ultimately entered the market with generic extended-release niacin even though it would make economic sense for Kos to launch an authorized generic and Kos had been planning to do so; of course, the harm to Barr of Kos' launching of an authorized generic would have been substantial. And, Barr explicitly agreed that it would not launch a generic equivalent of Niaspan until September 20, 2013.

b. **Co-Promotion Agreement.** For as long as Barr kept its generic equivalent of Niaspan off the market, as provided in the Settlement and Licensing Agreement, Kos agreed to pay Barr (through Duramed and DPSC, two Barr subsidiaries, which later became Teva Women's Health, Inc.) a royalty on all of Kos' sales of Niaspan and Advicor, another Kos drug.[15] Barr, Duramed, and DPSC agreed to promote Niaspan and Advicor to obstetricians, gynecologists, and other doctors specializing in women's health. The royalty that Kos agreed to pay to Barr was to be based upon overall sales of Niaspan and Advicor, regardless of whether the sales were generated by Barr's sales force, and provided another incentive for Barr not to disrupt brand Niaspan sales.

c. **License and Manufacturing Agreement.** Kos (and its subsidiary, Kos Life Sciences Inc.) made a non-refundable lump-sum payment to Barr, ostensibly as compensation for Barr's investment in developing FDA-approved manufacturing processes for Niaspan and Advicor. Kos (and Kos Life Sciences Inc.) also agreed to make quarterly payments to Barr for every quarter that Barr remained ready to manufacturer Niaspan and Advicor. Barr agreed to serve as a ready back-up supplier to Kos for those products, and agreed to sell them to Kos at an agreed-upon contract price. If Barr sold a generic equivalent of Niaspan to any third-party before September 20, 2013, Kos would have no further obligation to make quarterly payments to Barr.

95. The Exclusion Payment Agreement had two other notable provisions:

a. Kos and Barr agreed to do all things reasonably necessary to further the intent and purposes of the transactions contemplated by the Agreement.

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[14] This could happen, for example, if another generic manufacturer were to invalidate all of Kos' patents for Niaspan.

[15] *See supra* n. 12.

b. Kos and Barr agreed that either company could transfer its rights and obligations to a successor entity through a merger or other corporate takeover.

96. On April 12, 2005, and as envisioned by the Exclusion Payment Agreement, the patent court dismissed all of the patent infringement cases pending between Barr and Kos regarding Niaspan.

97. Under the Exclusion Payment Agreement, Kos (and its successors) has paid and continued to pay Barr (and later Teva) to not launch generic Niaspan until 2013. The payments have taken at least the following forms:

a. A lump sum payment, disguised as a "stand-by" payment to compensate Barr for being ready to manufacture Niaspan under the License and Manufacturing Agreement and that has far exceeded the value that Barr (and later Teva) provided to Kos (and its successors) by being ready to manufacture and supply Niaspan;

b. A functional equivalent of hundreds of millions of dollars in payments through forbearance by Kos (and its successors) in launching an authorized generic version of Niaspan during Barr's (and later Teva's) 180-days of exclusivity, which began on September 20, 2013, notwithstanding the facts that:

i. Kos had been planning to launch an authorized generic when faced with Barr's impending at-risk launch in 2005; and

ii. It makes economic sense for AbbVie to launch an authorized generic during Teva's 180-day exclusivity period (1) so that AbbVie can retain some of the sales that Teva's less expensive generic seeks to capture and (2) because AbbVie sacrifices profit by its forbearance.

c. Quarterly payments, disguised as payments to compensate Barr (and later Teva) for remaining ready to manufacture Niaspan under the License and Manufacturing Agreement and that far exceeded the value that Barr (and later Teva) provided by remaining ready to manufacture and supply Niaspan;

d. Quarterly royalty payments, disguised as compensation for Barr's (and later Teva's) work under the Co-Promotion Agreement and that were not legitimately tethered to and that far exceeded the value of the promotion efforts that Barr (and later Teva) was providing; and

e. A functional equivalent of tens of millions of dollars in payments through forbearance by Kos (and its successors) in launching an authorized generic version of Advicor notwithstanding the fact that it makes economic sense for AbbVie to launch an authorized generic (1) so that AbbVie can retain some of the sales that Barr's (and later Teva's) less expensive generic seeks to capture and (2) because AbbVie sacrifices profit by its forbearance.

98. All of these benefits had substantial value to Barr, and are compensation that it could not have obtained even if it had litigated and won the patent case. And these payments caused Barr to agree to stay out of the market longer than it otherwise would have done. Kos agreed to and did pay Barr to delay entry into the market.

99. In the years that followed entry of the Exclusion Payment Agreement, Barr (and later Teva) continued to receive those payments, and Barr (and later Teva) continued with its commitment that it would not launch a generic equivalent of Niaspan until September 20, 2013, more than eight years later.

100. Kos and Barr knew and intended that the Exclusion Payment Agreement would also prevent other generic companies from launching their own generic Niaspan before Barr did, thereby creating a bottleneck. As the first filer of an ANDA for a generic extended-release niacin, Barr/Teva is entitled to market its generic Niaspan for 180 days free from competition from other generic manufacturers. The operation of the parties' Exclusion Payment Agreement blocks any other generic Niaspan products from coming to market until 180 days after September 20, 2013, because the FDA will not approve any subsequently-filed ANDAs until the first-filer's exclusivity period has run, which will not occur until 180 days after Teva's actual launch.

101. But for the Exclusion Payment Agreement and the parties' ongoing adherence to and performance under that Agreement, generic competition for Niaspan would have occurred earlier and prices for both brand name Niaspan and generic extended-release niacin would have

been lower. Specifically:

a. Had Barr/Teva launched a generic equivalent of Niaspan at any time prior to September 20, 2013, the generic equivalent would have sold at lower prices than the prices at which Kos/Abbott/AbbVie was selling Niaspan. Direct purchaser plaintiffs would have paid lower prices – on both Niaspan and its generic AB-rated equivalents – than it otherwise paid.

b. Had Kos/Abbott/AbbVie launched its authorized generic equivalent of Niaspan when Barr/Teva launched, prices would have dropped even lower. As a matter of pharmaceutical economics, prices fall most dramatically when two or more generic equivalents of a drug are on the market alongside a brand name product. The Exclusion Payment Agreement prevented that generic competition from occurring and kept prices higher for the direct purchaser plaintiffs and the class.

c. Had Barr launched earlier at-risk, via settlement, or after victory in the patent litigation, other generic manufacturers would have been able to launch their own generic equivalents of Niaspan 181 days after Barr's launch, following the lapse of Barr's 180-day exclusivity period. By delaying Barr's launch until September 20, 2013, Kos and Barr sought to prevent – and has succeeded in preventing – other generic manufacturers from launching until 2014.

102. The purpose and effect of the Exclusion Payment Agreement was to suppress generic competition and to allow Kos/Abbott/AbbVie to charge higher prices for Niaspan.

103. Kos/Abbott/AbbVie's payments to Barr/Teva under this agreement have been substantial, and those payments have continued to involve significant sums, including the following:

a. In 2005, Kos paid Barr an "upfront fee" believed to be approximately $5 million (and supplemented by future "stand ready" quarterly fees) upon signing the settlement agreement in exchange for Barr's commitment to stand-by as an alternate supply source for Niaspan.

b. In 2006, Kos paid Barr approximately $45 million in royalty payments based on Kos' sales of Niaspan and Advicor, which was the "maximum annual royalty" the Exclusion Payment Agreement contemplated for the year.

c. In 2007, Kos paid Barr approximately $37 million, again the maximum annual royalty amount for that year under their co-promotion agreement for the sales of Niaspan and Advicor. On information and belief,

Kos/Abbott/AbbVie have made similar payments in subsequent years and paid Barr/Teva millions of dollars more than they otherwise would have paid for any services allegedly performed or to be performed under the Exclusion Payment Agreement.

d. Kos/Abbott/AbbVie refrained from introducing an authorized generic version of Niaspan in September 2013 when Barr/Teva finally launched its generic product, permitting Barr/Teva to earn tens, if not hundreds, of millions of dollars in additional revenues as the sole generic product on the market.

e. Kos gave Barr an opportunity to earn royalties on Kos' sales of its brand name Advicor prior to entry of a generic version to that product, even though Advicor had not been a part of the patent dispute that was being settled. The Advicor portion of the Exclusion Payment Agreement mirrored the Kos/Barr deal concerning Niaspan and constituted further payment to Barr for delaying the launch of generic Niaspan. Kos paid Barr millions of dollars more than it otherwise would have paid for any services allegedly performed or to be performed under the Exclusion Payment Agreement.

f. On information and belief, long after the Exclusion Payment Agreement was assigned following multiple corporate transactions, Kos/Abbott/AbbVie continued to pay Barr/Teva tens of millions of dollars every year, and those payments were still occurring in 2013.

104. Consistent with the Exclusion Payment Agreement, Kos and Barr took steps to fraudulently conceal their unlawful agreement to suppress generic competition.

105. When the Exclusion Payment Agreement was announced, both Kos and Barr repeatedly stated that the effect of the agreement was to bring a generic equivalent of Niaspan to the market in 2013, which they asserted was four years earlier than the expiration date of the last of Kos' patents ostensibly covering Niaspan. These statements were false and misleading – and both companies knew that they were false and misleading. The statements ignored the fact that Barr would have launched a generic equivalent of Niaspan at-risk in April of 2005. Thus, when Kos and Barr proclaimed that the Exclusion Payment Agreement would bring generic equivalents of Niaspan to market sooner than they otherwise would have arrived, both companies knew that the real purpose and effect of the Exclusion Payment Agreement was to delay generic

entry for many years.

106. When the Exclusion Payment Agreement was announced, Kos and Barr both refused to disclose the amount of the payments provided under the Agreement, because they had agreed to conceal the amounts of the payments that Barr was receiving. Repeatedly, when Wall Street analysts asked either company to disclose the amounts of the payments (or even the details for how the amounts would be calculated), the companies refused. Indeed, during conference calls with investment bank analysts, Kos representatives refused to answer direct questions from analysts in the financial community who asked about the financial terms of the payments that Kos was making to Barr (including an April 13, 2005 Conference Call, in which Barr's Chief Executive Officer Bruce Downey refused to provide details when asked about the financial terms of the Agreement, and an August 4, 2005 Conference Call, in which Kos' Interim Chief Financial Officer Juan Rodriguez refused to provide details of those financial terms).

107. Kos filed copies of contracts dated April 12, 2005 with the Securities and Exchange Commission as part of its 10-Q filing dated August 9, 2005, but the publicly-filed versions of those contracts redacted the financial terms regarding the payments. Neither company reported the amounts of the payments as separate items in their financial reports. (Additionally, the publicly-filed versions of the contracts contained recital clauses that falsely stated that the parties were hastening the entry of a generic equivalent of Niaspan, when in fact the parties had agreed to delay generic entry for many years.)

E. The FDA granted final approval to Barr on April 26, 2005, days after Kos and Barr entered the Exclusion Payment Agreement.

108. On April 26, 2005, shortly after the Exclusion Payment Agreement was signed, Barr received the clearance from the FDA that it had been expecting: the FDA granted final approval to Barr to manufacture and market generic Niaspan.

109. At the same time, given the existence of the Exclusion Payment Agreement, Barr disposed of the inventory that it had accumulated to be ready for its generic launch and took an inventory write-down in connection with its decision not to launch in April of 2005. Kos did the same thing for its inventory of an authorized generic version of Niaspan. (Kos had accumulated that inventory prior to the Exclusion Payment Agreement, on the expectation that it would begin selling an authorized generic Niaspan product to compete with Barr's generic Niaspan product as soon as Barr launched).

F. Abbott acquired Kos and continued the unlawful agreement to suppress generic competition.

110. In November of 2006, Abbott proposed to acquire control of Kos through a tender offer transaction. Abbott offered to pay Kos shareholders $78 per share, a 56% premium on the open market share price of $50 per share. At the time of the offer, Kos' portfolio of products was still heavily dependent on Niaspan, and Kos had few products in development. Thus, Niaspan – and the unlawful and ongoing Exclusion Payment Agreement preventing generic competition for it – was a central element of Abbott's valuation of Kos' business. Had generic versions of Niaspan entered the market prior to November 2006, Abbott would have not been willing to pay nearly as much as it ultimately paid for Kos.

111. Abbott's tender offer was successful, and Kos was merged into Abbott in December of 2006. As Kos' successor, Abbott stepped into the shoes of Kos with respect to the ongoing unlawful Exclusion Payment Agreement with Barr. Barr continued to refrain from entering the market with a generic equivalent of Niaspan, staying off the market until the agreed upon launch date on September 20, 2013, and Abbott continued to make the agreed-upon payments to Barr. In this way, both parties continued with the unlawful Exclusion Payment Agreement that suppressed and continues to suppress generic competition for Niaspan.

112. Upon the completion of the merger, Abbott joined the ongoing unlawful course of conduct – and joined the unlawful agreement, collusion, and conspiracy – with respect to the suppression of generic competition for Niaspan. Abbott did not withdraw from that conspiracy and instead continued to participate in and take affirmative steps to perpetuate it.

113. To the extent that the Exclusion Payment Agreement had any minimal lawful value to Kos in the form of co-promotion services or backup supply arrangements, those considerations had even less value to Abbott: Abbott was a substantially larger enterprise than Kos was, had an even larger promotion force, and had no use for additional supply capacity. The Exclusion Payment Agreement was valuable to Abbott because the Agreement was postponing Barr's launch of a generic equivalent of Niaspan, and Abbott was willing to continue to pay Barr for that ongoing suppression of generic competition.

114. Because it was substantially larger, Abbott was better able to exploit the market advantages created by the ongoing unlawful Exclusion Payment Agreement to suppress generic competition. After Abbott took over the Niaspan business, sales of Niaspan increased significantly. Annual U.S. retail sales of Niaspan more than doubled between 2006 and 2012, from $474 million to $1.03 billion.[16]

G. Teva acquired Barr and continued the unlawful agreement to suppress generic competition.

115. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva. Teva continued to follow the ongoing unlawful Exclusion Payment Agreement then in place with Abbott. Teva continued to refrain from entering the market with a generic equivalent of Niaspan, agreeing to hold off until September 20, 2013, and Abbott continued to make the

[16] Annual sales of Niaspan between 2006 and 2012 were: $474 million in 2006; $546 million in 2007; $639 million in 2008; $717 million in 2009; $794 million in 2010; $1.13 billion in 2011; and $1.03 billion in 2012.

agreed-upon payments to Teva.

116. Because of the acquisition, Teva also owned (either directly or indirectly) Barr's first-filer rights. Accordingly, no other generic company will be able to launch a generic equivalent of Niaspan until Teva has had a 180-day period as the exclusive generic seller of extended-release niacin. Following Teva's launch of a generic equivalent of Niaspan on September 20, 2013, no other generic company can introduce a generic equivalent of Niaspan until March 2014.

117. Upon the completion of its acquisition of Barr, Teva joined the ongoing unlawful course of conduct – and joined the unlawful agreement, collusion, and conspiracy – with respect to the suppression of generic competition for Niaspan. Teva did not withdraw from that conspiracy and instead continued to participate in it.

H. Abbott acted to preserve the unlawful agreement to suppress generic competition.

118. Between 2006 and 2012, Abbott took additional steps to ensure that nothing happened to disrupt the Exclusion Payment Agreement or allow generic competition for Niaspan before September of 2013.

119. For example, Abbott knew that if any other generic drug manufacturer obtained a final judgment following a court decision of invalidity, unenforceability, or non-infringement of the Niaspan patents, then Teva's 180-day exclusivity period would begin to run. Teva would be motivated to launch its generic product immediately, before the agreed-upon launch date of September 20, 2013, cutting short the defendants' unlawful scheme. Recognizing this risk, Abbott acted aggressively to prevent such a disruption.

120. On March 6, 2009, Abbott filed a patent infringement lawsuit against Lupin Limited in the United States District Court for Delaware (docketed as 09-cv-152). Abbott alleged that Lupin, a generic manufacturer, had infringed Abbott's patents by filing a Paragraph

IV certification as part of an effort to gain approval for and launch a generic equivalent of Niaspan. On June 13, 2012, Abbott and Lupin stipulated to a dismissal of the lawsuit. The court never ruled on whether Lupin had infringed Abbott's patents or issued any final judgment on Lupin's claims that Abbott's patents were invalid or unenforceable.

121. After March 2009, Abbott filed numerous additional patent infringement lawsuits against generic manufacturers that had filed Paragraph IV certifications with respect to a possible generic equivalent of Niaspan. Abbott/AbbVie settled six of those cases and dismissed them by stipulation, with no final judgments entered on the infringement, validity, or enforceability of Abbott/AbbVie's patents.

a. In *Abbott Laboratories v. Sun Pharmaceuticals Indus. Ltd.*, No. 10-CV-112 (D. Del.), the court scheduled trial for mid-2013 but the parties settled in February 2013, before the court issued any substantive rulings;

b. In *Abbott Laboratories v. Sandoz, Inc.*, No. 10-CV-538 (D. Del.), the parties settled in March 2013, one month before trial, and again before the court issued any substantive rulings;

c. In *Abbott Laboratories v. Amneal Pharmaceuticals LLC*, No. 12-CV-235 (D. Del.), the parties settled in March 2013, before the court issued any substantive rulings;

d. In *Abbott Laboratories v. Cadila Healthcare Ltd.*, No. 12-CV-0065 (D. Del.), the parties settled on August 14, 2013, before the court issued any substantive rulings;

e. In *Abbott Laboratories v. Kremers Urban Pharmaceuticals, Inc.*, No. 12-CV-703 (D. Del.), the parties settled on September 26, 2013 before the court issued any substantive rulings; and

f. In *Abbott Laboratories v. Watson Laboratories, Inc.*, No. 12-CV-324 (D. Del.), the parties settled on September 12, 2013 before the court issued any substantive rulings.

122. One other case remains pending, and it is still in discovery, with no decisions on the merits of the alleged infringement, the validity, or the enforceability of Abbott/AbbVie's patents: *Abbott Laboratories v. Mylan, Inc.*, No. 12-CV-257 (D. Del.).

123. In pursuing and settling these lawsuits, Abbott/AbbVie has been able to avoid the entry of any definitive ruling that would accelerate the date for the 180-day exclusivity for Teva. Through delay and through settlements, Abbott/AbbVie has ensured that no final judgment has been entered on non-infringement, invalidity, or unenforceability of the relevant patents.

124. Abbott/AbbVie has prosecuted these patent cases as part of its covenant to take steps necessary to preserve the agreement to suppress generic competition, as part of the Exclusion Payment Agreement. Abbott/AbbVie's conduct in these lawsuits was – and is – part of and in furtherance of its ongoing unlawful agreement with Teva to suppress generic competition in the market for Niaspan.

I. Abbott spun off Niaspan to AbbVie and AbbVie continued with the unlawful agreement to suppress generic competition.

125. In 2012, Abbott announced that it was spinning off most of its prescription drug business into a new company, AbbVie. That spin-off became effective as of January 1, 2013. As Abbott's successor, AbbVie has stepped into the shoes of Abbott with respect to the ongoing unlawful Exclusion Payment Agreement with Teva. Teva continued to refrain from launching a generic equivalent of Niaspan until September 20, 2013 and AbbVie has continued to make the agreed-upon payments to Teva.

126. Upon the transition of the Niaspan business from Abbott to AbbVie on or about on January 1, 2013, AbbVie joined the ongoing unlawful course of conduct – and joined the unlawful agreements, collusion, and conspiracy – with respect to the suppression of generic competition for Niaspan. AbbVie did not withdraw from that conspiracy and instead continued to participate in it.

J. The unlawful agreement to suppress generic competition is ongoing and continues to cause injury.

127. Until September 20, 2013, no generic equivalent of Niaspan was on the market in

the United States. Even then, when Teva began selling generic Niaspan, AbbVie has continued to adhere to its agreement not to launch an authorized generic. With only one generic product on the market, AbbVie continues to sell Niaspan at artificially-inflated prices, and the direct purchaser plaintiffs have been denied the lower prices that full generic competition would have brought to the market. This lack of full generic competition is the direct result of the ongoing unlawful Exclusion Payment Agreement (and the subsequent settlements with other generic competitors) that will continue to dampen competition at least into 2014.

128. The unlawful agreement has also resulted in higher prices for Teva's extended-release niacin. Since September of 2013, when Teva began selling generic Niaspan, Teva has been able to charge higher prices than would have been charged but for the Exclusion Payment Agreement and AbbVie's promise not to launch an authorized generic of Niaspan. Thus, Teva has been able to launch and sell its generic at a higher price than it otherwise would have without competitive pressure from an authorized generic version of Niaspan during the most lucrative time immediately following Teva's launch.

129. Because the alleged conspiracy was both self-concealing and material facts were affirmatively concealed and misrepresented by the defendants and their co-conspirators, the direct purchaser plaintiffs and members of the class had no knowledge of the alleged conspiracy, or of facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

130. As a result of the defendants' fraudulent concealment, all applicable statutes of limitations affecting the direct purchaser plaintiffs' claims and the claims of the class have been tolled.

131. Alternatively, during the four-year period prior to the filing of this complaint, the

defendants' unlawful conduct and violation of the antitrust laws has been ongoing, payments were being made from Abbott and AbbVie to Teva to compensate Teva for refraining from entering the market with generic Niaspan prior to September 20, 2013, and the direct purchaser plaintiffs have continued to suffer injury with every purchase and on every day that the defendants' unlawful Exclusion Payment Agreement not to compete has remained in place. During the applicable limitations period, the defendants have operated under an ongoing Exclusion Payment Agreement to suppress generic competition, and the direct purchaser plaintiffs have been injured by the defendants' conduct.

K. The unlawful agreement to suppress generic competition harms competition, injures the direct purchaser plaintiffs, and causes damages.

132. On May 9, 2003, the FDA issued its tentative approval for Barr's ANDA for a generic equivalent of the 1000 mg dosage of Niaspan. On June 13, 2003, the FDA issued its tentative approval for Barr's ANDA for a generic equivalent of the 500 mg and 750 mg dosages of Niaspan. The FDA issues tentative approval only when it determines that an ANDA would otherwise be ready for final approval but for a thirty-month stay.

133. But for the defendants' overarching, anticompetitive, and ongoing scheme to delay generic Niaspan competition in the United States, a generic equivalent of Niaspan would have been available in the United States far earlier than September 20, 2013, the first date that generic Niaspan actually became available.

134. Additionally, but for the illegal conduct described in the complaint, Kos would have launched its own authorized generic Niaspan product at the same time that Barr launched its extended-release niacin, resulting in additional price competition for Niaspan and its generic equivalents during Barr's 180-day exclusivity period.

135. But for the anticompetitive, illegal, and ongoing conduct alleged in this

complaint, the direct purchaser plaintiffs and members of the class would have paid less for their extended-release niacin. As a result, the defendants, by their conduct, have injured the direct purchaser plaintiffs and the class by causing them to pay substantial overcharges – potentially hundreds of millions of dollars – on their purchases of Niaspan. And at all times, the defendants have shared in the illicit profits that have resulted from the artificially-inflated prices for Niaspan.

136. The active ingredient in Niaspan is extended-release niacin. Its pharmacological profile, and thus its side effect and efficacy profile, is different than other prescription and non-prescription medicines that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Niaspan, cannot be automatically substituted for Niaspan by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Niaspan, and thus are not economic substitutes for, nor reasonably interchangeable with, Niaspan.

137. Defendants' unlawful Exclusion Payment Agreement was designed to and did in fact: (a) preclude the entry of less expensive generic versions of extended-release niacin in the United States; (b) fix, raise, maintain or stabilize the prices of extended-release niacin products; (c) permit Kos/Abbott/AbbVie to maintain a monopoly in the United States for extended-release niacin; and (d) allocate 100% of the United States extended-release niacin market to Kos/Abbott/AbbVie.

138. Defendants violated §§ 1 and 2 of the Sherman Act through their conspiracy to improperly maintain and extend their market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of extended-release niacin.

CLASS ACTION ALLEGATIONS

139. Direct purchaser plaintiffs bring this action on behalf of themselves and, under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a class defined

as follows:

> All persons or entities in the United States and its territories who purchased brand name Niaspan or generic extended-release niacin directly from any of the defendants at any time during the period April 27, 2005, through the date that the anticompetitive effects of the defendants' challenged conduct cease.

Excluded from the class are the defendants, their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

140. Members of the class are so numerous that joinder is impracticable. Direct purchaser plaintiffs believe that the class numbers in the dozens at least and is geographically spread across the nation. Further, the class is readily identifiable from information and records in the possession of the defendants.

141. Direct purchaser plaintiffs' claims are typical of the claims of the members of the class. Direct purchaser plaintiffs and all members of the class were damaged by the same wrongful conduct by the defendants, *i.e.,* they paid artificially inflated prices for extended-release niacin and were deprived the benefits of competition from less-expensive generic versions of Niaspan as a result of the defendants' wrongful conduct.

142. Direct purchaser plaintiffs will fairly and adequately protect and represent the interests of the class. Direct purchaser plaintiffs' interests are coincident with, and not antagonistic to, those of the class.

143. Direct purchaser plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving the pharmaceutical industry.

144. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is

inherent in the defendants' wrongful conduct.

145. Questions of law and fact common to the class include:

a. whether, the defendants conspired to suppress generic competition to Niaspan;

b. whether, pursuant to the Agreement, Barr/Teva agreed to delay its entry into the market with generic Niaspan;

c. whether, pursuant to the Agreement, Kos/Abbott/AbbVie compensated Barr/Teva;

d. whether Kos/Abbott/AbbVie's compensation to Barr/Teva was for a purpose other than delayed entry of generic Niaspan;

e. whether Kos/Abbott/AbbVie's compensation to Barr/Teva was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

f. whether the Agreement created a bottleneck to generic competition;

g. whether the Agreement is illegal under the rule of reason;

h. whether the defendants' challenged conduct suppressed generic competition to Niaspan;

i. whether the defendants' challenged conduct harmed competition in the market(s) in which Niaspan is sold;

j. whether Kos/Abbott/AbbVie possessed market or monopoly power over Niaspan;

k. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

l. whether the activities of the defendants as alleged herein have substantially affected interstate commerce;

m. whether, and to what extent, the defendants' conduct caused antitrust injury to the business or property of the direct purchaser plaintiffs and the members of the class in the nature of overcharges; and

n. the quantum of overcharges paid by the class in the aggregate.

146. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class treatment will permit a large number of similarly

situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

147. Direct purchaser plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

INTERSTATE COMMERCE

148. At all material times, Kos/Abbott/AbbVie manufactured, promoted, distributed, and sold substantial amounts of Niaspan in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

149. At all material times, the defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Niaspan and/or its AB-rated generics.

150. In furtherance of their efforts to monopolize and restrain competition in the market for extended-release niacin, the defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of the defendants were within the flow of and have substantially affected interstate commerce.

MONOPOLY POWER AND MARKET DEFINITION

151. At all relevant times, Kos/Abbott/AbbVie had monopoly power over extended-release niacin because it had the power to maintain the price of the drug it sold as Niaspan at

supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Niaspan, with the exception of AB-rated generic versions of Niaspan.

152. "[T]he 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level."[17] And a firm that lacks monopoly power is not "likely to pay 'large sums' to induce 'others to stay out of its market.'"[18]

153. Prior to the entry of AB-rated generic versions of Niaspan, a small but significant, non-transitory price increase for Niaspan by Kos and later Abbott would not have caused a significant loss of sales.

154. For example, the 2011 AIM-HIGH study published in New England Journal of Medicine, "found that Niaspan didn't prevent heart attacks in patients whose cholesterol was controlled with a statin[.]" The study was even "stopped early after the National Institutes of Health said the rate of strokes in patients on the drug was more than double those taking a statin alone." This negative study resulted in a decline of approximately one-third in the monthly number of Niaspan prescriptions written. However, despite this decline in the usage and perceived benefits of Niaspan, Abbott and AbbVie were able to raise the price of Niaspan by 37 percent during this time period – from $3.50 per pill to $4.78 per pill – and keep their revenue from Niaspan steady at approximately $120 million per month. That is, Niaspan suffered a substantial decrease in demand because of negative clinical studies yet Abbott and AbbVie were able to overcome that simply by raising Niaspan's price – something they could not profitably have done if they did not possess monopoly power.

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[17] *Actavis*, 133 S. Cti. At 2236 (citation omitted).

[18] *Id.*

155. Niaspan does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Niaspan. Indeed, Kos/Abbott/AbbVie has never lowered the price of Niaspan in response to the pricing of other branded treatments for mixed lipid disorders (or the generic versions of such medications).

156. Because of its labeling, Niaspan is differentiated from all products other than AB-rated generic versions of Niaspan.

157. Kos/Abbott/AbbVie needed to control only Niaspan and its AB-rated generic equivalents, and no other products, in order to maintain the price of Niaspan profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Niaspan would render Kos/Abbott/AbbVie unable to profitably maintain its current prices of Niaspan without losing substantial sales.

158. Kos/Abbott/AbbVie also sold Niaspan at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

159. Defendants have had, and exercised, the power to exclude and restrict competition to Niaspan and AB-rated generics.

160. Kos/Abbott/AbbVie at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

161. Direct purchaser plaintiffs allege that the relevant market is extended-release niacin (*i.e.*, Niaspan and its AB-rated generic equivalents). During the period relevant to this case, Kos/Abbott/AbbVie has been able to profitably maintain the price of extended-release niacin well above competitive levels.

162. The relevant geographic market is the United States and its territories.

163. At all relevant times, Kos/Abbott/AbbVie's market share in the relevant market was and remains 100%, implying a substantial amount of monopoly power.

EFFECTS ON COMPETITION, AND THE DAMAGES CLAIMED IN THIS ACTION

164. Barr's ANDA received final approval from the FDA on April 26, 2005. Were it not for the Exclusion Payment Agreement, generic Niaspan products would have entered the market some time thereafter, and, in any event, before September 20, 2013.

165. Defendants' Exclusion Payment Agreement has delayed generic competition and unlawfully enabled Kos/Abbott/AbbVie to sell Niaspan without generic competition. But for the defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Niaspan substantially earlier than September 20, 2013.

166. The generic manufacturers seeking to sell generic Niaspan had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

167. Defendants' Exclusion Payment Agreement, which delayed introduction into the United States marketplace of generic versions of Niaspan, have caused the direct purchaser plaintiffs and the class to pay more than they would have paid for extended-release niacin absent the defendants' illegal conduct.

168. Typically, generic versions of brand name drugs are initially priced significantly below the corresponding brand name drug to which they are AB-rated. As a result, upon generic entry, some or all of the direct purchases of brand name drugs are rapidly substituted for generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic

manufacturers, and, correspondingly, the brand name drug continues to lose even more to the generics.

169. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

170. But for the Exclusion Payment Agreement, direct purchasers, such as the direct purchaser plaintiffs and members of the class, would have paid less for extended-release niacin by (a) substituting purchases of less-expensive AB-rated generic Niaspan for their purchases of more-expensive brand name Niaspan, (b) receiving discounts on their remaining brand name Niaspan purchases, and (c) purchasing generic Niaspan at lower prices sooner.

171. Moreover, due to the defendants' Exclusion Payment Agreement, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Niaspan, and/or (b) challenging the validity or infringement of the Niaspan patents in court.

172. As discussed above, but for the Exclusion Payment Agreement, Kos/Abbott/AbbVie would have launched its own authorized generic Niaspan product during Barr/Teva's 180-day exclusivity period, resulting in additional price competition for Niaspan.

173. Thus, the defendants' unlawful conduct deprived the direct purchaser plaintiffs and the class of the benefits of competition that the antitrust laws were designed to ensure.

174. During the relevant period, the direct purchaser plaintiffs and other members of the class purchased substantial amounts of Niaspan directly from Kos/Abbott/AbbVie. As a result of the defendants' illegal Exclusion Payment Agreement as alleged herein, the direct

purchaser plaintiffs were compelled to pay, and did pay, artificially inflated prices for their extended-release niacin requirements. Direct purchaser plaintiffs and the other class members paid prices for extended-release niacin that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic Niaspan instead of expensive brand name Niaspan; (2) class members paid artificially inflated prices for extended-release niacin.

175. As a consequence, the direct purchaser plaintiffs and other members of the class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

176. This complaint alleges a continuing course of unlawful conduct (including conduct within the limitations period), and the direct purchaser plaintiffs and the members of the class have been and continue to be harmed by the defendants' conduct to the present day.[19]

CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 2 (Conspiracy to Monopolize)

177. Direct purchaser plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

178. At all relevant times, Kos and later Abbott possessed substantial market power (*i.e.*, monopoly power). They possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the market for extended-release niacin.

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[19] The alleged anticompetitive conduct by Kos detailed here is not the first time that Kos engaged in unlawful behavior to increase its revenues and profits from Niaspan. Kos and Abbott agreed in 2010 to pay $41 million to the federal government and entered into a deferred prosecution agreement to resolve allegations of Kos paying illegal kickbacks and off-label marketing of Niaspan. Kos also agreed to the filing of criminal information in the Middle District of Louisiana, charging the company with one count of conspiracy to violate the federal anti-kickback statute by agreeing to pay physicians kickbacks in exchange for their writing prescriptions for Kos drugs.

179. Through the Exclusion Payment Agreement with Barr, Kos conspired to maintain Kos' monopoly power in the relevant market in order to block and delay market entry of extended-release niacin, *i.e.*, AB-rated generic versions of Niaspan. The unlawful Exclusion Payment Agreement between Kos and Barr allocated all sales of extended-release niacin in the United States to Kos; delayed the sales of generic Niaspan products; and fixed the price at which the direct purchaser plaintiffs and members of the class would pay for extended-release niacin at the higher, brand name price.

180. The goal, purpose and/or effect of the Exclusion Payment Agreement was to maintain and extend Kos' monopoly power in the United States market for extended-release niacin in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Exclusion Payment Agreement prevented and/or delayed generic competition to Niaspan and enabled Kos to continue charging supracompetitive prices for Niaspan without a substantial loss of sales.

181. Kos and Barr knowingly and intentionally conspired to maintain and enhance Kos' monopoly power in the relevant market.

182. Kos and Barr specifically intended that their Exclusion Payment Agreement would maintain Kos' monopoly power in the relevant market, and injured the direct purchaser plaintiffs and the class thereby.

183. Kos and Barr each committed at least one overt act in furtherance of the conspiracy.

184. As a direct and proximate result of the defendants' concerted conduct, as alleged herein, the direct purchaser plaintiffs and the class were harmed.

CLAIM II: VIOLATION OF 15 U.S.C. § 1
(Agreement Restraining Trade)

185. Direct purchaser plaintiffs hereby incorporate each preceding and succeeding

paragraph as though fully set forth herein.

186. In or about April 2005, and at times prior to the formal execution thereof, Kos and Barr entered into the Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Kos (and later Abbott/AbbVie) paid Barr/Teva substantial consideration in exchange for Barr/Teva's agreement to delay bringing its generic version of Niaspan to the market, the purpose and effect of which were to: (a) allocate 100% of the market for extended-release niacin in the United States to Kos/Abbott/AbbVie; (b) prevent the sale of generic versions of Niaspan in the United States, thereby protecting Niaspan from any generic competition until September 20, 2013; and (c) fix the price at which direct purchasers would pay for extended-release niacin at supracompetitive levels.

187. The Agreement harmed the direct purchaser plaintiffs and the class as set forth above.

188. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

189. Kos/Abbott/AbbVie and Barr/Teva are liable for the Agreement under a rule of reason standard.

190. There is and was no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payment that outweighs its harmful effect. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

191. As a direct and proximate result of Kos/Abbott/AbbVie's and Barr/Teva's anticompetitive conduct, as alleged herein, the direct purchaser plaintiffs and the class were harmed as aforesaid.

DEMAND FOR JUDGMENT

WHEREFORE, the direct purchaser plaintiffs, on behalf of themselves and the class, respectfully request that the Court:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare the direct purchaser plaintiffs as the representatives of the class;

b. Enter joint and several judgments against the defendants and in favor of the direct purchaser plaintiffs and the class;

c. Adjudge the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), to be an unlawful restraint of trade in violation of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

d. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

e. Award the direct purchaser plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law.

JURY DEMAND

Pursuant to Fed. Civ. P. 38, the direct purchaser plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Respectfully submitted,

Dated: January 15, 2014

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